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VIRTUAL
EXPERIENCE



EVEREST-I: One-year Optilume™ BPH Catheter System Efficacy and Safety Experience



The Optilume™ BPH Catheter System

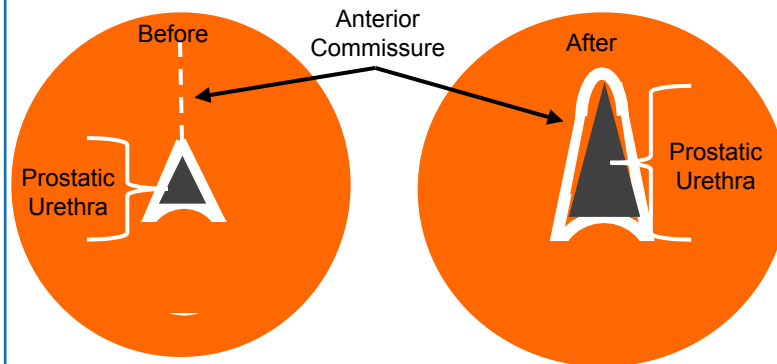
- The Optilume™ BPH Catheter System is the first-ever minimal invasive treatment that provides TURP-like results without cutting, burning, steaming or leaving a permanent implant behind.
- The system creates a TransUrethral Anterior commissurotomy of the Prostate (TUAP).
- The distal end of the catheter has a uniquely shaped semi-compliant inflatable balloon that is coated with a proprietary coating containing the active pharmaceutical paclitaxel. The drug coating covers the working length of the balloon body.
- The Optilume BPH System is comprised of a pre-dilation un-coated balloon catheter and a post dilation drug coated balloon (DCB) catheter.



Step 1

Mechanical Dilation

- Optilume™ BPH Catheter System is used to perform a **TransUrethral Anterior commissurotomy** of the **Prostate (TUAP)**. The low-pressure dilation alleviates obstructive BPH by opening and expanding the anterior commissure increasing the size of the prostatic urethra.
- Multiple device sizes are available to provide customized treatment based on prostate size



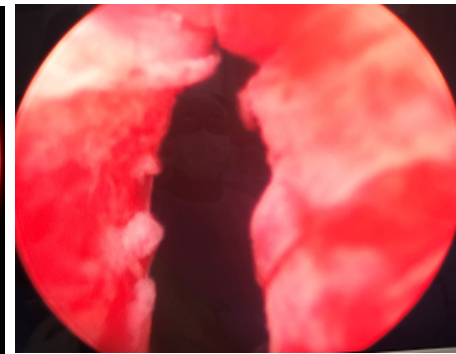
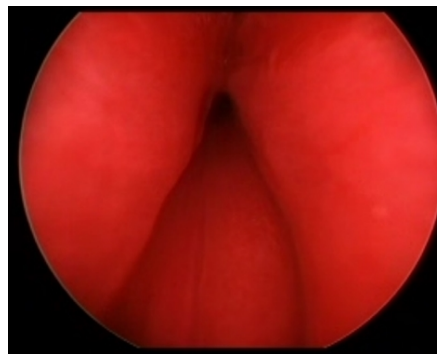
Step 2

Drug Delivery

- Balloon circumferentially delivers an anti-proliferative drug (Paclitaxel) that maintains the opening of the newly split tissue

Optilume Procedure

- Minimizes or eliminates the common side effects associated with other surgical BPH procedures.



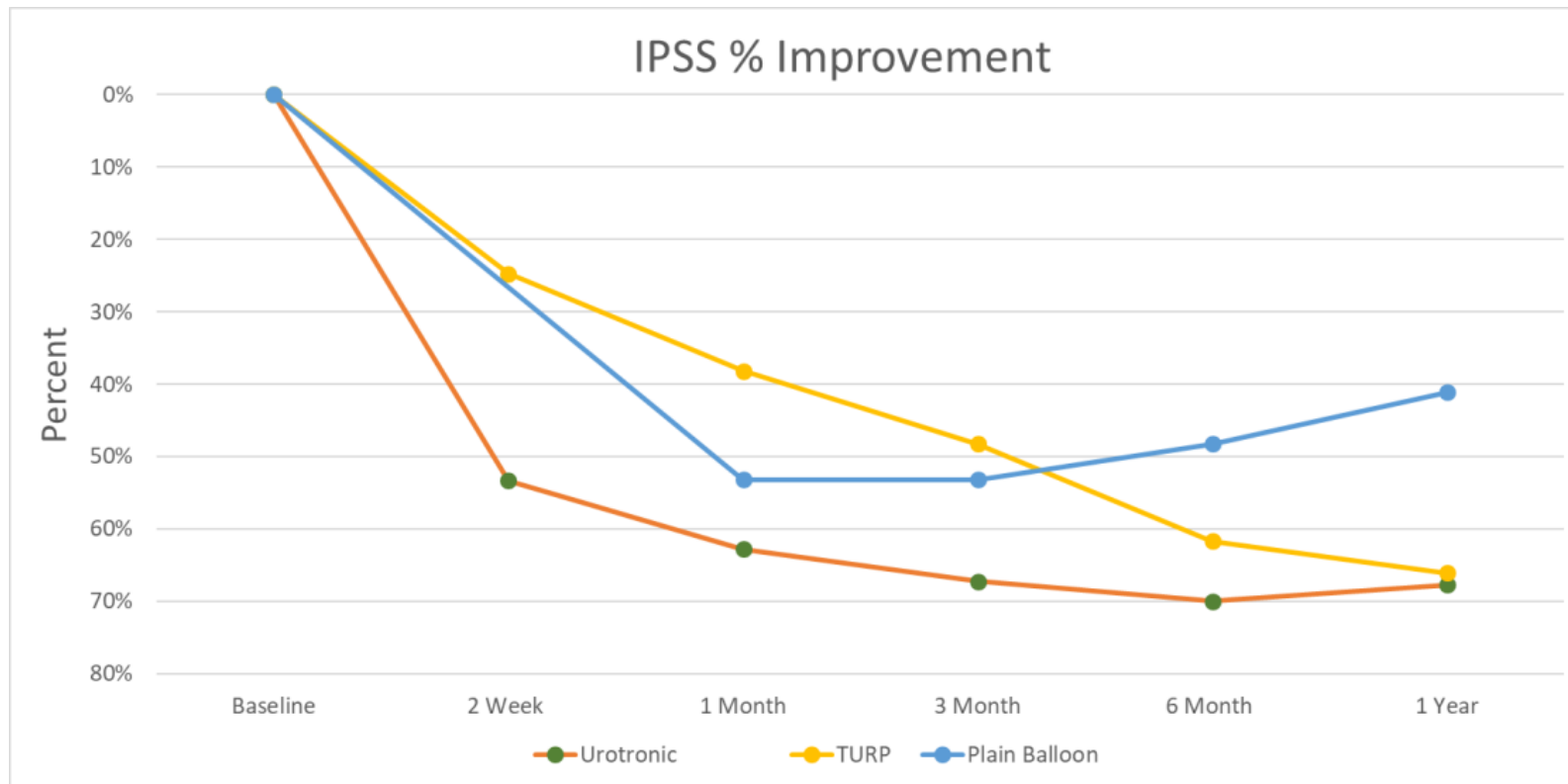


Optilume BPH Catheter Clinical Data

- The Optilume™ BPH Catheter System is currently under investigation in the prospective, randomized, double blinded PINNACLE trial in 20 US sites.
- A pilot study, EVEREST-I, has completed enrollment and the treatment of 80 subjects with BPH at six Latin American investigational sites, two in Panama and four in the Dominican Republic. Subject follow-up is currently ongoing. As of February 10, 2020, 73 subjects had completed the 1-Year follow-up visit and 22 subjects had completed the 2-Year follow-up visit.
- The study is GCP compliant with Steven Kaplan, M.D. Professor of Urology, Icahn School of Medicine at Mount Sinai in NYC is the study Principle Investigator.



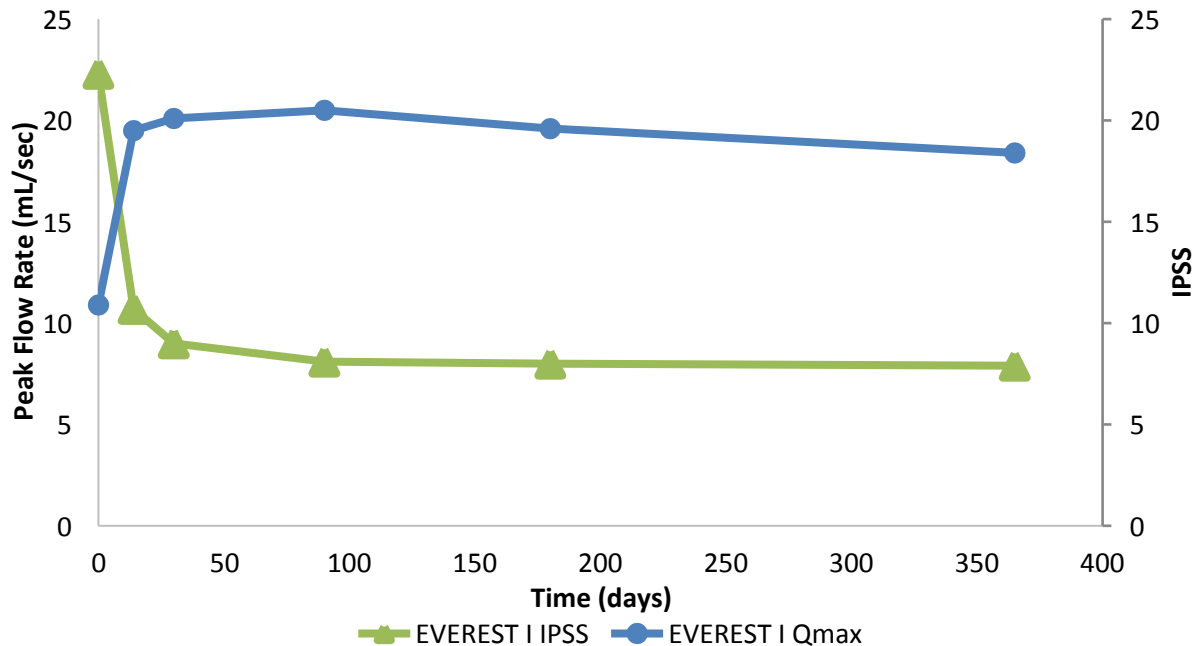
IPSS - Plain Balloon vs. Optilume Drug Coated Balloon





EVEREST STUDY RESULTS

Change in IPSS and Qmax Through 1 Year (ITT)

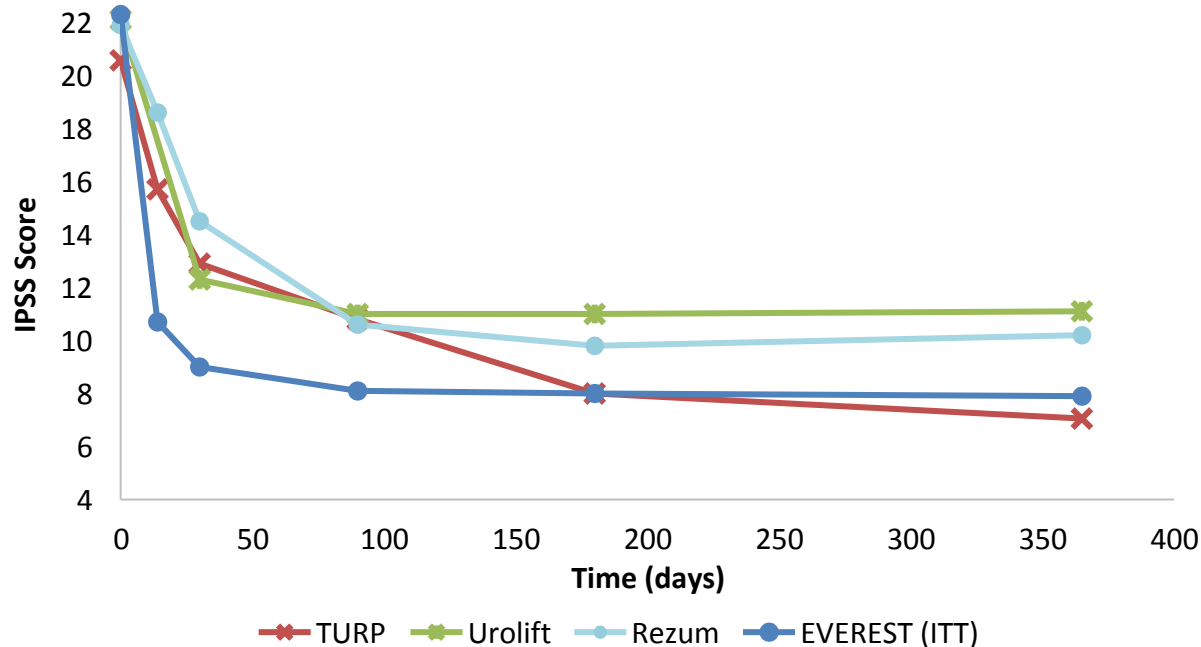


- Significant reduction in IPSS and increase in Qmax post-procedure sustained through 1 year.



EVEREST IPSS RESULTS

Change in IPSS Over Time by Treatment Type



- Improvement in symptoms more pronounced than other MIST therapies^{1,2} and more immediate than TURP^{3,4}.

¹Roehrborn CG, Gange SN, Shore ND, et al. *J Urol*. 2013;190:2161-67

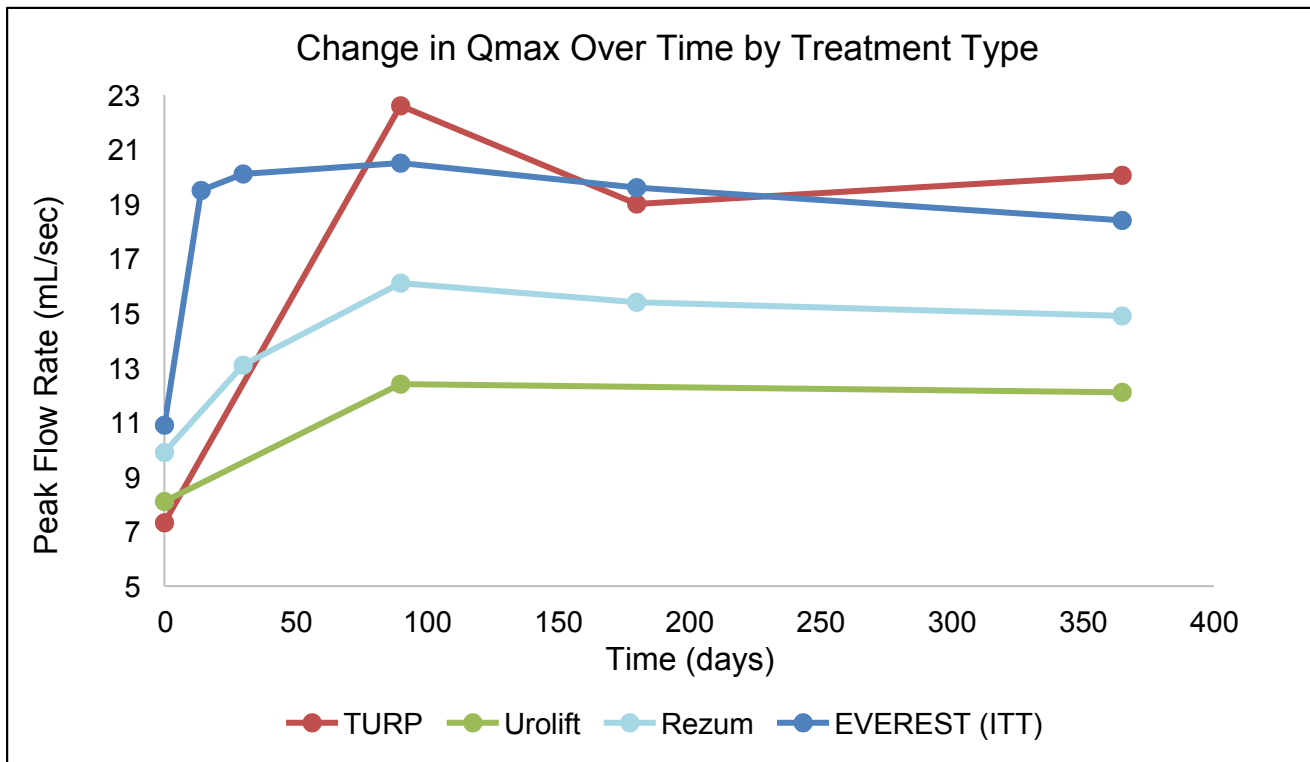
²McVary KT, Gange SN, Gittelman MC, et al. *J Urol*. 2016;195:1529-38

³Sonksen J, Barber NJ, Speakman MJ, et al. *Eur J Urol*. 2015;68:643-52.

⁴Kumar N, Vasudeva P, Kumar A, Singh H. *LUTS*. 2018;10(1):17-20



EVEREST QMAX RESULTS



- Improvement in symptoms more pronounced than other MIST therapies^{1,2} and more immediate than TURP^{3,4}.

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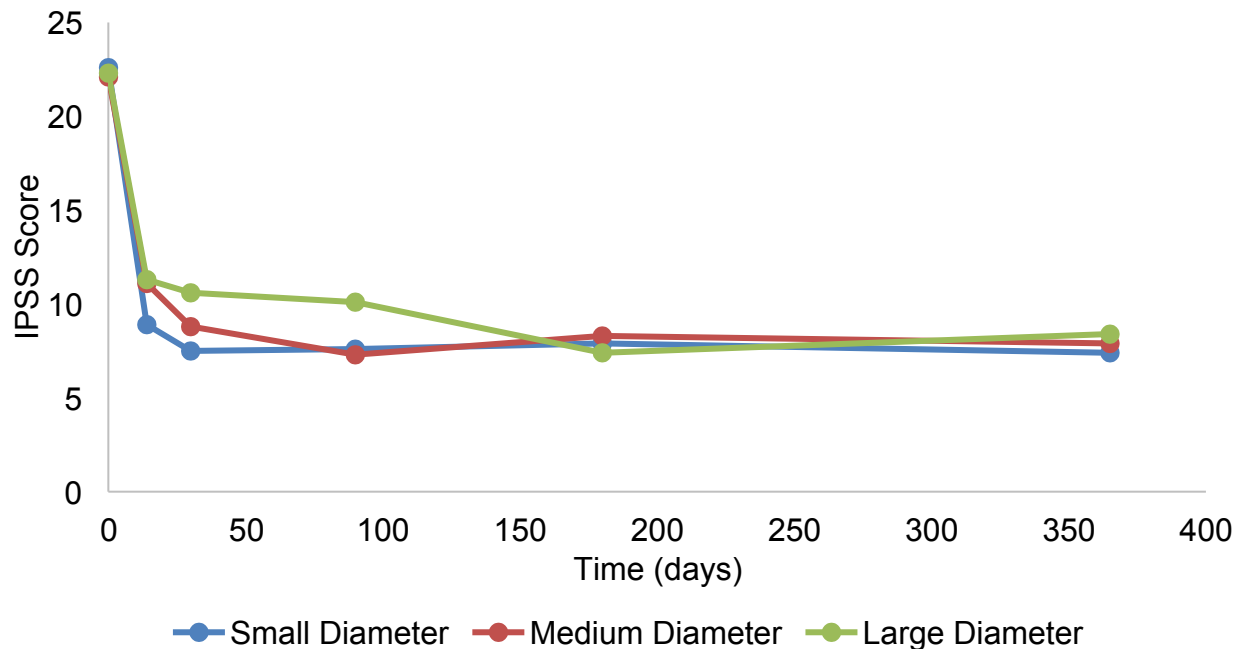
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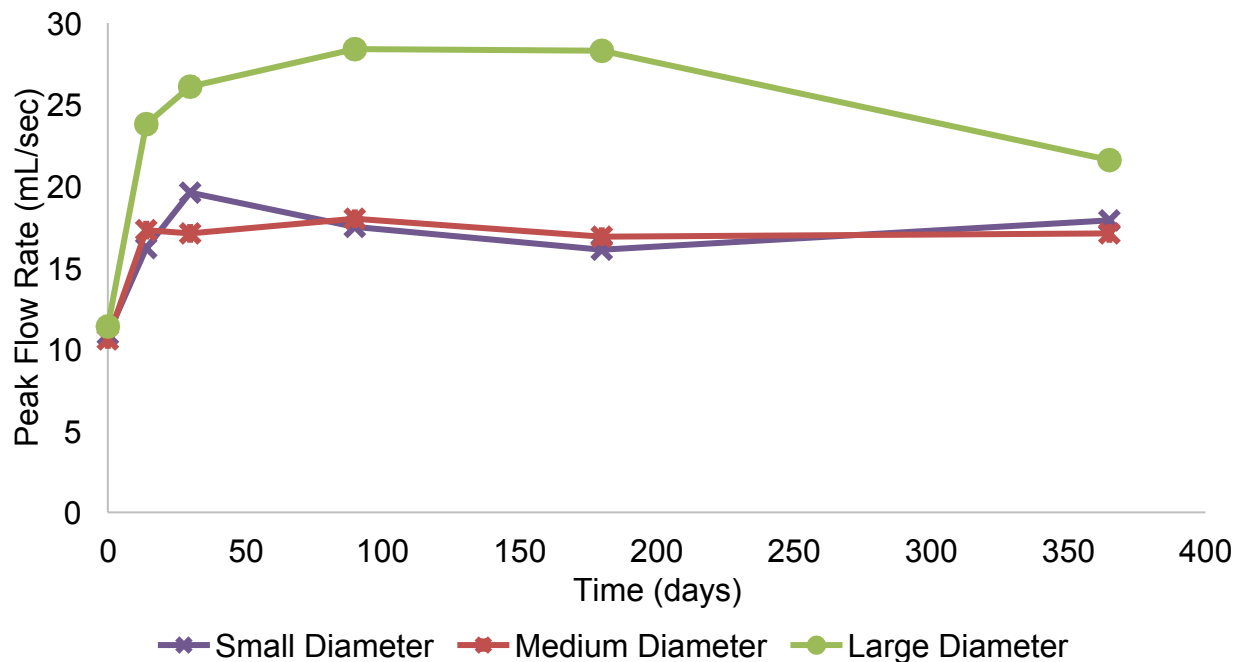
Change in IPSS Over Time by Device Size



- Symptomatic improvement similar for all balloon sizes.
- Largest balloon size achieved maximum symptom relief by 6 months, similar to TURP and Rezum.
- Smallest balloon size achieved maximum symptom relief by day 30.



Change in Qmax Over Time by Device Size

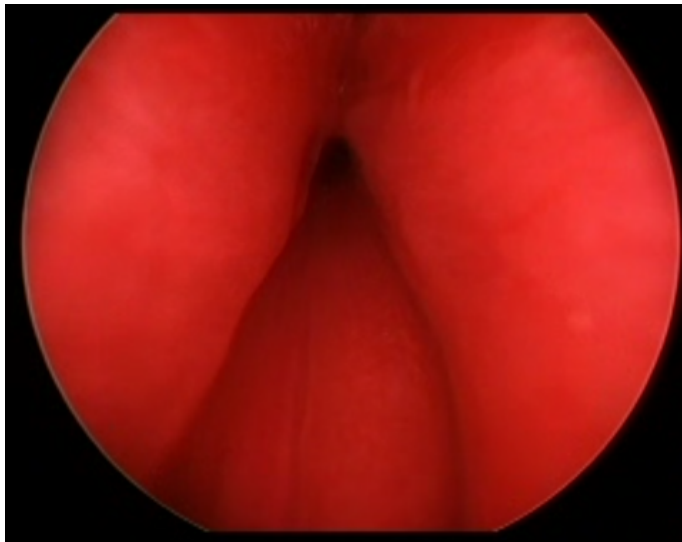


- Largest balloon size showed significant increase in Qmax immediately post procedure, with slight deterioration seen at 1 year.
- Small/Medium balloons showed large increase in Qmax to ~17 mL/sec, sustained through 1 year.



Optilume BPH Patient 1yr Follow-up Cysto

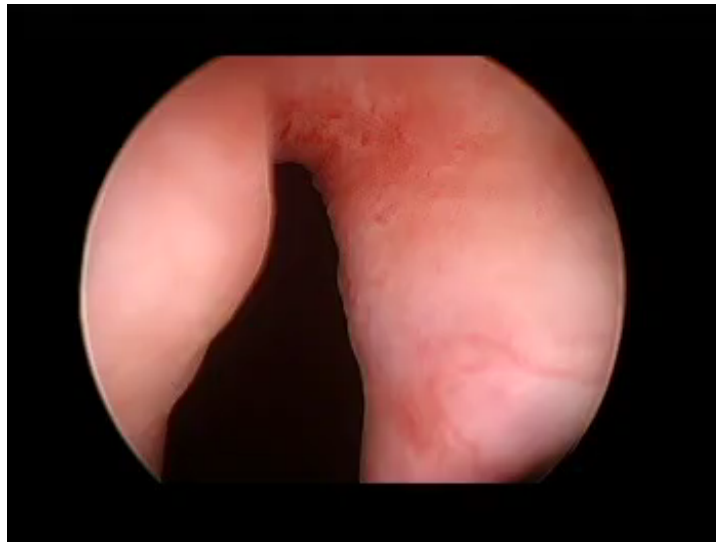
Everest Patient 505-008



Baseline

Qmax 11 ml/sec

IPSS 15



1yr Follow-up

Qmax 21 ml/sec

IPSS 3

Scroll over image to play video

Note: The open anterior split or commissurotomy could not be fully captured in a single cystoscopic image